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Registration Decision

Hankin Ozone Generator

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Publications
Pest Management Regulatory Agency
Health Canada
2720 Riverside Drive
A.L. 6605C
Ottawa, Ontario
K1A 0K9

Internet: pmra_publications@hc-sc.gc.ca
www.pmra-arla.gc.ca
Facsimile: 613-736-3758
Information Service:
1-800-267-6315 or 613-736-3799
pmra_infoserv@hc-sc.gc.ca

Canada

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Overview

Registration Decision for Hankin Ozone Generator

Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, is granting full registration for the sale and use of the Hankin Ozone Generator, which discharges ozone to control fouling from zebra mussels in service water intake pipes.

An evaluation of available scientific information found that, under the approved conditions of use, the product has value and does not present an unacceptable risk to human health or the environment.

This product was first proposed for registration in the consultation document[1] Proposed Registration Decision PRD2008-14, *Hankin Ozone Generator*. This Registration Decision[2] describes this stage of the PMRA's regulatory process for Hankin Ozone Generator and summarizes the Agency's decision and the reasons for it. The PMRA received no comments on PRD2008-14, and this decision is consistent with the proposed registration decision stated in the document.

For more details on the information presented in this Registration Decision, please refer to Proposed Registration Decision PRD2008-14, *Hankin Ozone Generator,* as it contains a detailed evaluation of the information submitted in support of this registration.

What Does Health Canada Consider When Making a Registration Decision?

The key objective of the *Pest Control Products Act* is to prevent unacceptable risks to people and the environment from the use of pest control products. Health or environmental risk is considered acceptable[3] if there is reasonable certainty that no harm to human health, future generations or the environment will result from use or exposure to the product under its conditions of registration. The Act also requires that products have value[4] when used according to label directions. Conditions of registration may include special precautionary measures on the product label to further reduce risk.

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1 "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.

2 "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

3 "Acceptable risks" as defined by subsection 2(2) of *Pest Control Products Act*.

4 "Value" as defined by subsection 2(1) of the *Pest Control Products Act* is "...the product's actual or potential contribution to pest management, taking into account its conditions or proposed conditions of registration, and includes the product's (a) efficacy; (b) effect on host organisms in connection with which it is intended to be used; and (c) health, safety and environmental benefits and social and economic impact."

To reach its decisions, the PMRA applies modern, rigorous risk-assessment methods and policies. These methods consider the unique characteristics of sensitive subpopulations in humans (e.g. children) as well as organisms in the environment (e.g. those most sensitive to environmental contaminants). These methods and policies also consider the nature of the effects observed and the uncertainties when predicting the impact of pesticides. For more information on how the PMRA regulates pesticides, the assessment process and risk-reduction programs, please visit the PMRA's website at www.pmra-arla.gc.ca.

What Is the Hankin Ozone Generator?

The Hankin Ozone Generator is a device used to control zebra mussel fouling in service water intake pipes. In Canada, this registration is limited to the service water intake pipes of the Lennox Generating Station belonging to Ontario Power Generation. The device produces ozone on site that is then injected into the process water near the main intake pipes in order to control fouling from zebra mussels.

Health Considerations

Can Approved Uses of the Hankin Ozone Generator Affect Human Health?

The Hankin Ozone Generator is unlikely to affect your health when used according to the operating instructions (for the ozonated water system [OWS] in the Lennox Generating Station) and the label directions.

Potential exposure to ozone generated by the Hankin Ozone Generator may occur when operating the ozone generator or when working in the Lennox Generating Station. When assessing health risks, two key factors are considered: the levels at which no health effects occur and the levels to which people may be exposed. The dose levels used to assess risks are established to protect the most sensitive human population (e.g. children and nursing mothers). Only uses for which the exposure is well below levels that cause no effects in animal testing are considered acceptable for registration.

Ozone is highly acutely toxic to rats when inhaled. Ozone did not cause eye irritation in animals. No information on skin irritation from ozone is available, but the compound could cause irritation. However, exposure levels that would severely affect the respiratory tract would be reached prior to skin irritation occurring. No information on skin sensitization from ozone is available, but it has caused asthma-like effects in animals exposed to various types of allergens.

There was no evidence that ozone can affect reproductive performance. Ozone has caused effects on behaviour, the brain, and depressed growth rates and body weights in offspring of female rats and mice, although at concentrations that have

caused respiratory effects in adult animals. The acute, short-term and long-term effects of exposure to ozone are mainly confined to the lung and respiratory tract and include inflammation of the airways, decreased lung function and effects on the clearance of inhaled contaminants from the lung. Associations between acute exposure to non-occupational ambient outdoor exposure to ozone (i.e. its effects on the respiratory tract, hospitalizations, emergency department visits for respiratory symptoms, asthma and increased mortality rates) have been reported in epidemiology studies of human populations.

Ozone has been reported to be genotoxic in microorganisms, plants, and cultured mammalian and human cells. However, results of studies with laboratory animals are inconclusive. While there is some evidence of lung tumours following ozone exposure in strains of mouse susceptible to this type of tumour and in female mice from another strain exposed for a lifetime, there is no evidence of carcinogenicity from studies conducted with rats and hamsters. Also, the results of a limited number of epidemiological studies of ozone and cancer are inconclusive. Other international assessments of ozone have concluded that the available published scientific studies do not support ambient ozone as a pulmonary carcinogen.

While ozone from the Hankin Ozone Generator has the potential to induce toxic effects (primarily on the respiratory tract) in animals and humans, exposure to levels that could induce these effects is very unlikely to occur due to the control measures in place at the Lennox Generating Station. These control measures include ozone analyzers, alarm systems, ventilation, and manual and automatic procedures for shutting down ozone production. These control measures are calibrated to occupational exposure limits and ambient air quality criteria for ozone are regulated under the Ontario *Occupational Health and Safety Act* and the Ontario *Environmental Protection Act*, respectively.

In addition, it is proposed that the label of the Hankin Ozone Generator include the statement, "Danger Poison", and the precautionary statements, "Fatal if inhaled. DO NOT inhale/breathe gas. For workers who are checking readings on ozone in air analyzers using hand-held monitors under high or very high ozone alarm conditions, use positive pressure air lines with a mask or self-contained breathing apparatus" and "Prevent access by children and unauthorized personnel." It is also proposed that the label include first aid statements describing procedures to follow if skin, clothing, eye or inhalation exposure occurs.

Residues in Water and Food

Dietary risks from food and water are not of concern.

There are no food-related uses of the Hankin Ozone Generator.

Under the proposed use, the Hankin Ozone Generator would inject ozone into the service water system of the Lennox Generating Station to prevent biofouling and settlement of zebra mussels. A relatively low concentration of ozone in water is required for this purpose and discharges of ozonated water from the generating station must meet effluent requirements specified in an Ontario Ministry of the Environment (OME) Certificate of Approval issued for the OWS. In addition, the high reactivity of ozone means that it is unlikely that the low concentrations of ozone in water discharged from the generating station could affect the quality of drinking or recreational water from Lake Ontario.

Occupational Risks From Exposure to Ozone from the Hankin Ozone Generator

Occupational risks are not of concern when the Hankin Ozone Generator is used according to the operating instructions (for the ozonated water system in the Lennox Generating Station) and the label directions.

The chemical technician responsible for operation of the OWS and other workers in the Lennox Generating Station have the potential to be exposed to ozone in air from the Hankin Ozone Generator and ozonated water from the service water systems in the generating station. To control occupational exposures to airborne ozone, a combination of ozone analyzers, warning lights, audible alarms, automatic exhaust fans and ventilators, and manual and automatic shutdown procedures for ozone production are employed in the generating station. Because these control measures are calibrated to occupational exposure limits and ambient air quality criteria for ozone regulated under the Ontario *Occupational Health and Safety Act* and the Ontario *Environmental Protection Act*, respectively, it is unlikely that workers in the generating station will be exposed to levels of ozone that could adversely affect their health.

It is unlikely that workers in the plant will be exposed to levels of ozone in water that could adversely affect human health for the following reasons.

- Only a low concentration of ozone is used in the service water systems.
- Ozone is highly reactive in water.
- Levels of ozone in water discharged from the generating station must meet OME effluent requirements.

In addition, a statement on the acute inhalation risk from ozone, precautionary statements on avoiding inhalation exposure and preventing access to unauthorized

personnel, and first aid statements describing procedures to follow if skin, clothing, eye or inhalation exposure occurs are proposed for the label of the Hankin Ozone Generator.

Because of the control measures employed in the Lennox Generating Station, bystander exposure to ozone is expected to be negligible. Therefore, potential health risks to bystanders are not of concern.

Environmental Considerations

What Happens When Ozone From the Hankin Ozone Generator Is Introduced Into the Environment?

The active ingredient, ozone, is released into the environment through discharge of process water treated with ozone. The discharge water does not contain a high enough concentration of ozone to cause detrimental effects to aquatic biota in the immediate vicinity of the discharge. The ozone is expected to dissipate rapidly once in the environment.

Value Considerations

The Hankin Ozone Generator is a device that produces ozone within the service water intake pipes to prevent fouling from zebra mussels.

When properly operated, the Hankin Ozone Generator will produce an ozone residual within the service water intake pipes that effectively reduces the degree of fouling from zebra mussels. The device generates ozone by corona discharge through concentrated oxygen, and the ozone is then injected into the cooling water at a maximum continuous rate of 0.5 ppm. At this treatment rate, the number of zebra mussels settling on the surfaces of intake pipe is greatly reduced. In the absence of control, the zebra mussels settle in densely packed colonies, which impede the flow of cooling water and contributes to corrosion. Prior to treating with ozone, the Lennox Generating Station used chlorine to control zebra mussel fouling. While also effective, the chlorine treatment produced undesirable byproducts. Ozone provides an effective treatment without these byproducts.

Measures to Minimize Risk

To protect human health and the environment risk-reduction measures for the Lennox Generating Station OWS include a series of air analyzers, warning lights, audible alarms, automatic exhaust fans and ventilators, and manual and automatic shutdown procedures for ozone production. The analyzers and alarm systems are calibrated to occupational exposure limits and ambient emission limits regulated under the Ontario *Occupational Health and Safety Act* and the Ontario *Environmental Protection Act*, respectively.

In addition, labels of registered pesticide products include specific instructions for use. Directions include risk-reduction measures to protect human and environmental health. These directions must be followed by law.

The key risk-reduction measures being proposed on the label of the Hankin Ozone Generator to address potential risks identified in this assessment are as follows.

Key Risk-Reduction Measures

Human Health

Because ozone is highly acutely toxic via inhalation, the label is to include the statement "Danger Poison" and the precautionary statements, "Fatal if inhaled. DO NOT inhale/breathe gas. For workers who are checking readings on ozone in air analyzers using hand-held monitors under high or very high ozone alarm conditions, use positive pressure air lines with a mask or self-contained breathing apparatus" and "Prevent access by children and unauthorized personnel."

Other Information

1. The relevant test data on which the decision is based (as referenced in this document) are available for public inspection, upon application, in the PMRA's Reading Room (located in Ottawa). For more information, please contact the PMRA's Pest Management Information Service by phone (1-800-267-6315) or by e-mail (pmra_infoserv@hc-sc.gc.ca).

2. Any person may file a notice of objection[5] regarding this registration decision within 60 days from the date of publication of this Registration Decision. For more information regarding the basis for objecting (which must be based on scientific grounds), please refer to the PMRA's website (Requesting a Reconsideration of Decision, http://www.pmra-arla.gc.ca/english/pubreg/reconsideration-e.html) or contact the PMRA's Pest Management Information Service by phone (1-800-267-6315) or by e-mail (pmra_infoserv@hc-sc.gc.ca).

[5] As per subsection 35(1) of the *Pest Control Products Act*.

References

A. LIST OF STUDIES/INFORMATION SUBMITTED BY REGISTRANT

1.0 Impact on Human and Animal Health

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PMRA 1381700 2006, Operation of the Ozonated Water System, DACO: 5.2

PMRA 1381701 2000, Continuous Ozonation of Service Water at Lennox G.S. – Overview of System Location and Operation, DACO: 5.2

PMRA 1381703 2000, Continuous Ozonation of Service Water at Lennox G.S. – Overview of Off-Gas Destruct Unit, DACO: 5.2

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2.0 Impact on the Environment

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PMRA 1381700 2006, Operation of the Ozonated Water System

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PMRA 1381703 2000, Continuous Ozonation of Service Water at Lennox G.S. – Overview of Off-Gas Destruct Unit

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PMRA 1381710 2000, Electrical Safety Authority – Product Approval Certificate

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3.0 Value

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B. ADDITIONAL INFORMATION CONSIDERED

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